## REMARKS/ARGUMENTS

Claims 1-3 are pending in the application. Claim 4-12 have been added.

Claim 1 has been amended to recite, *inter alia*, a device for transdermal drug delivery, comprising a skin patch having a plurality of drug reservoirs containing a drug, the reservoirs being arranged in a matrix such that when the device is placed in contact with the skin of a recipient, a plurality of sharp hydration gradients are created along the peripheries of the reservoirs.

Claim 2 has been amended to recite, *inter alia*, a method with the same limitations as claim 1.

Support for the above amendments can be found in Figures 3, 5, 7 and 10, and paragraphs [0022] – [0024].

Claim 3 has been amended to recite the method of claim 2 in which the reservoirs comprise a gel. Support for this can be found on paragraphs [0034] – [0035].

New claim 4 is directed to the method of claim 2 in which the reservoirs have a skin contact area of less than 1 $cm^2$. Support for this amendment can be found on paragraphs [0021] and [0029].

New claim 5 is directed to the method in which the reservoirs are isolated from each other. New claim 6 is directed to the method in which the reservoirs are isolated by the areas between the reservoirs being filled with an inert material. New claim 7 is directed to the method of claim 6 in which the inert material is air. Support for these claims can be found on paragraphs [0037] and figures 7 and 10.

New claim 8 is directed to a device of claim 1 in which the reservoirs comprise a gel. Support for this can be found on paragraphs [0034] – [0035].

New claim 9 is directed to a device of claim 1 in which the reservoirs have a skin contact area of less than 1 $cm^2$. Support for this can be found on paragraphs [0034] – [0035].

New claim10 is directed to the device in which the reservoirs are isolated from each other; new claim 11 is directed to the device in which the reservoirs are isolated by the areas between the reservoirs being filled with an inert material. New claim 12 is directed to the device in claim 11 in which the inert material is air. Support for these claims can be found on paragraphs [0037] and figures 7 and 10.

The rejection of claims 1-3 and new claims 4-10 under 35 USC 102(b) as being anticipated by Turner (US Pat. No. 5,462,743) or under 35 USC 102(e) as being anticipated by Matloub (US Appln. No. US2005/0147654), are respectfully traversed.

As an preliminary matter, it should be noted that Applicants claimed invention differs from both prior art references in that Applicants' reservoirs have sufficient structural characteristics to their walls allowing them to form close contact with the skin underneath the walls. This contact prevents the skin underneath the reservoir walls (and areas between the reservoir wells) from being exposed to the drug, and thereby allows this skin to exist at a lower state of hydration, compared to the skin directly underneath the reservoir wells. Thus, a sharp hydration gradient is formed at the interface of the skin areas that contacts the formulation and the areas that do not. In contrast, both prior art devices are incapable of forming such sharp hydration gradients because a) their reservoir walls are made of absorbent material (*i.e.*, both Turner and Matloub) and/or b) the material surrounding the reservoirs are made of an adhesive permeable material (*i.e.*, (Turner); or c) the structures surrounding the reservoirs are microchannels that allow free movement of fluid between them and the reservoirs (*i.e.*, Matloub).

Amended claims call for, *inter alia*, a device or method where the transdermal drug delivery, is comprised of a skin patch having a plurality of drug reservoirs containing a drug, the reservoirs being arranged in a matrix such that when the device is

placed in contact with the skin of a recipient, a plurality of sharp hydration gradients are created along the peripheries of the reservoirs.

Turner discloses multiple embodiments. Embodiments in Fig. 1, 2, 3, 16 and 17 do not disclose "a plurality of reservoirs" as required by Applicants claims. These embodiments, although showing multiple channels **20**, show only one reservoir **16**, and therefore do not anticipate.

The remaining embodiments in Turner's Fig. 4-15, however, are not capable of providing the "sharp hydration gradients along the peripheries of the reservoir" as required by Applicants claims for at least two reasons: First, these devices have reservoirs that are bodies **42** made entirely of a porous support matrix. Because the reservoir walls are also themselves made of this porous material, there is no physical barrier preventing the drug in the reservoirs from hydrating areas under the reservoir walls or areas between the reservoirs. Accordingly, sharp hydration gradients are not formed. Second, hydration gradients cannot be formed because the wall/material immediately surrounding these absorbent reservoir bodies are made of an adhesive material **18**. This adhesive material is unlikely to result in the intimate contact necessary to prevent drug leaking underneath the adhesive material from the neighboring reservoir/bodies. Moreover, this adhesive material is disclosed to allows passage of drug to hydrate areas of the skin below the material (see col. 12, lines 20-21).

Similarly in Matloub the reservoirs are actual bodies **60** made of flexible foam material (See paragraphs [0037-0038]). Furthermore, between these reservoirs are microchannels **30**, which are used to fill the reservoirs, to wit:

> "FIG. 4 shows the therapeutic agent **70** filling or partially filling the open cells of the polymer foam **60** into the flexible polymer foam **60** and polymer enrobing material **50** from the microchannels **30**. The therapeutic agent easily migrates throughout the foam (due to the open-cell foam properties) and enrobing material. The open foam cells **62** are filled, or partially

> filled with the therapeutic agent **70** and are ready to release the therapeutic agent into the skin when the strip **90** and liner **80** are removed and the composite sheet is applied to the skin. Typically, when silicone is used as the polymer enrobing material, it will adhere to its skin surface because of its tacky nature. (See paragraph [0044])

Accordingly, Matloub's reservoirs are not capable of forming a device "such that when the device is placed in contact with the skin of a recipient, a plurality of sharp hydration gradients are created" because the channels surrounding the reservoirs allow free passage of drug into the surrounding reservoirs. In fact, such free flow would essentially result in all of Matloub's multiple reservoirs being connected together, and acting like a single reservoir the disadvantages of which Applicants' seek to overcome with their claimed invention (see specifications paragraphs [0024]). This is also evident from the fact that drug may also be delivered via these microchannels (see paragraph 0048]).

Claims 6 and 11 are also not anticipated by either Turner or Matloub. These claims are directed, *inter alia*, to embodiments where areas between the reservoirs are filled with an inert material. In contrast, in Turner's embodiments the areas between reservoirs are not inert but are made of adhesive material **18** capable of flow (see col. 12, line 22). In Matloub's embodiments the areas between the reservoirs are not inert but comprise of open channels **30**.

Claims 7 and 12 are also not anticipated by either Turner or Matloub. Claims 7 and 12 are directed, *inter alia*, to embodiments where areas between the reservoirs are left empty so that the skin is exposed only to air. In contrast, in Turner's embodiments are not left empty but have adhesive material **18**. In Matloub's embodiments, the skin areas between the reservoirs are not empty but exposed to drugs because the channels **30** that surround the reservoirs are used to either load or deliver the drug (see also paragraph [0048]).

In view of the foregoing, applicant believes that the application is in condition for allowance and respectively solicits a Notice of Allowance. The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-3881, under Order No. 1279-385. If an extension of time is required please consider this a petition and charge any additional fees which may be required to deposit account No. 50-3881. A duplicate copy of this paper is enclosed.

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Respectfully submitted,

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